

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1-48. (canceled)

49. (Previously presented) A pharmaceutical dosage unit comprising an effective amount of modafinil wherein at least about 10% of the total cumulative modafinil particles are smaller than about 25 microns in diameter and more than about 5% of the total cumulative particles are more than about 200 microns in diameter, wherein said pharmaceutical dosage unit is bioequivalent to a modafinil dosage unit in which at least about 95% of the particles have diameters less than about 200 microns.

50. (Original) The pharmaceutical dosage unit of claim 49 wherein at least about 15% of the total cumulative modafinil particles are smaller than or equal to about 25 microns in diameter and more than about 5% of the total cumulative particles are more than about 200 microns.

51. (Original) The pharmaceutical dosage unit of claim 49 wherein at least about 20% of the total cumulative modafinil particles are smaller than or equal to about 25 microns in diameter and more than about 5% of the total cumulative particles are more than about 200 microns.

52. (Original) The pharmaceutical dosage unit of claim 49 wherein at least about 25% of the total cumulative modafinil particles are smaller than or equal to about 25 microns in diameter and more than about 5% of the total cumulative particles are more than about 200 microns.

53. (Previously presented) The pharmaceutical dosage unit of claim 49 wherein at least about 95% of the total cumulative modafinil particles are smaller than 400 microns in diameter.

54. (Original) The pharmaceutical dosage unit of claim 49 wherein at least about 95% of the total cumulative modafinil particles are smaller than 400 microns in diameter.

55. (Original) The pharmaceutical dosage unit of claim 50 wherein at least about 95% of the total cumulative modafinil particles are smaller than 400 microns in diameter.

56. (Original) The pharmaceutical dosage unit of claim 51 wherein at least about 95% of the total cumulative modafinil particles are smaller than 400 microns in diameter.

57. (Original) The pharmaceutical dosage unit of claim 52 wherein at least about 95% of the total cumulative modafinil particles are smaller than 400 microns in diameter.

58. (Previously presented) The pharmaceutical dosage unit of any one of claims 49-52 wherein the amount of modafinil is about 100 mg.

59. (Previously presented) The pharmaceutical dosage unit of any one of claims 49-52 wherein the amount of modafinil is about 200 mg.

60. (Original) The pharmaceutical dosage unit of claim 53 wherein more than about 10% of the total cumulative particles are more than about 200 microns.

61. (Original) The pharmaceutical dosage unit of claim 54 wherein more than about 10% of the total cumulative particles are more than about 200 microns.

62. (Original) The pharmaceutical dosage unit of claim 55 wherein more than about 10% of the total cumulative particles are more than about 200 microns.

63. (Original) The pharmaceutical dosage unit of claim 56 wherein more than about 10% of the total cumulative particles are more than about 200 microns.

64. (Original) The pharmaceutical dosage unit of claim 57 wherein more than about 10% of the total cumulative particles are more than about 200 microns.

65. (Original) The pharmaceutical dosage unit of claim 53 wherein more than about 15% of the total cumulative particles are more than about 200 microns.

66. (Original) The pharmaceutical dosage unit of claim 54 wherein more than about 15% of the total cumulative particles are more than about 200 microns.

67. (Original) The pharmaceutical dosage unit of claim 55 wherein more than about 15% of the total cumulative particles are more than about 200 microns.

68. (Original) The pharmaceutical dosage unit of claim 56 wherein more than about 15% of the total cumulative particles are more than about 200 microns.

69. (Original) The pharmaceutical dosage unit of claim 57 wherein more than about 15% of the total cumulative particles are more than about 200 microns.

70. (Original) The pharmaceutical dosage unit of claim 53 wherein more than about 20% of the total cumulative particles are more than about 200 microns.

71. (Original) The pharmaceutical dosage unit of claim 54 wherein more than about 20% of the total cumulative particles are more than about 200 microns.

72. (Original) The pharmaceutical dosage unit of claim 55 wherein more than about 20% of the total cumulative particles are more than about 200 microns.

73. (Original) The pharmaceutical dosage unit of claim 56 wherein more than about 20% of the total cumulative particles are more than about 200 microns.

74. (Original) The pharmaceutical dosage unit of claim 57 wherein more than about 20% of the total cumulative particles are more than about 200 microns.

75. (Original) The pharmaceutical dosage unit of claim 53 wherein more than about 25% of the total cumulative particles are more than about 200 microns.

76. (Original) The pharmaceutical dosage unit of claim 54 wherein more than about 25% of the total cumulative particles are more than about 200 microns.

77. (Original) The pharmaceutical dosage unit of claim 55 wherein more than about 25% of the total cumulative particles are more than about 200 microns.

78. (Original) The pharmaceutical dosage unit of claim 56 wherein more than about 25% of the total cumulative particles are more than about 200 microns.

79. (Original) The pharmaceutical dosage unit of claim 57 wherein more than about 25% of the total cumulative particles are more than about 200 microns.

80. (Original) The pharmaceutical dosage unit of claim 53 wherein more than about 30% of the total cumulative particles are more than about 200 microns.

81. (Original) The pharmaceutical dosage unit of claim 54 wherein more than about 30% of the total cumulative particles are more than about 200 microns.

82. (Original) The pharmaceutical dosage unit of claim 55 wherein more than about 30% of the total cumulative particles are more than about 200 microns.

83. (Original) The pharmaceutical dosage unit of claim 56 wherein more than about 30% of the total cumulative particles are more than about 200 microns.

84. (Original) The pharmaceutical dosage unit of claim 57 wherein more than about 30% of the total cumulative particles are more than about 200 microns.

85. (Original) The pharmaceutical dosage unit of any one of claims 60-84 wherein the amount of modafinil is about 100 mg.

86. (Original) The pharmaceutical dosage unit of any of claims 60-84 wherein the amount of modafinil is about 200 mg.

87-114. Canceled.

115. (Previously presented) An oral dosage unit of modafinil wherein:
more than about 5% of the modafinil particles in the dosage unit have diameters greater than about 200 microns; and
less than about 95% of the modafinil particles in the dosage unit have diameters less than about 200 microns;

wherein said dosage unit is bioequivalent to a modafinil dosage unit in which at least about 95% of the particles have diameters less than about 200 microns; and wherein said dosage unit is prepared from a pharmaceutical composition prepared by blending a first and a second portion of solid modafinil particles wherein said first portion has a pre-determined particle size range and said second portion has a pre-determined particle size range that is different from that of the first portion.

116. (Previously presented) An oral dosage unit according to claim 115 wherein about 5% to about 35% of the modafinil particles are more than 220 microns in diameter, and about 95% to about 65% of the modafinil particles are less than 220 microns in diameter.

117. (Previously presented) An oral dosage unit according to claim 116 wherein about 10% to about 30% of the modafinil particles are more than 220 microns in diameter.

118. (Previously presented) An oral dosage unit according to claim 117 wherein about 15% to about 30% of the modafinil particles are more than 220 microns in diameter.

119. (Previously presented) An oral dosage unit according to claim 118 wherein about 20% to about 30% of the modafinil particles are more than 220 microns in diameter.

120. (Previously presented) An oral dosage unit according to claim 119 wherein about 25% to about 30% of the modafinil particles are more than 220 microns in diameter.

121. (Previously presented) An oral dosage unit according to claim 116 wherein about 20% of the modafinil particles are more than about 250 microns in diameter, and about 80% of the modafinil particles are between about 10 microns and 100 microns in diameter.

122. (Previously presented) An oral dosage unit according to claim 116 wherein the dosage form is a tablet or capsule.

123. (Previously presented) An oral dosage unit according to claim 122 further comprising one or more pharmaceutically acceptable excipient.

124. (Previously presented) An oral dosage unit according to claim 116 wherein the dosage unit releases at least 80% of the modafinil in 45 minutes in a 0.1 N HCl solution.

125. (Previously presented) A method of treating a condition using modafinil, the method of treating comprising:

providing an oral dosage unit according to any one of claims 115 to 124.

126. (Previously presented) A method according to claim 125, wherein said condition comprises one or more of narcolepsy and idiopathic hypersomnia.

127. (Previously presented) An oral dosage unit according to claim 115, wherein said dosage form contains 100 mg of modafinil, and is bioequivalent to a 100 mg modafinil dosage unit in which at least about 95% of the particles are smaller than about 200 microns.

128. (Previously presented) An oral dosage form according to claim 115, wherein said dosage unit contains 200 mg of modafinil, and is bioequivalent to a 200 mg modafinil dosage form in which at least about 95% of the particles are smaller than about 200 microns.

129. (Previously presented) An oral dosage unit according to claim 128, that is bioequivalent to the modafinil drug product identified by the FDA as the reference listed modafinil drug.

130. (Previously presented) A method of altering the somnolent state of a mammal, said method comprising administering to said mammal an effective amount of an oral dosage unit of any one of claims 115 to 124 or 127 to 129.

131. (Previously presented) A method for enhancing alertness or increasing regularity of sleep rhythms in a mammal said method comprising administering to said mammal an oral dosage unit of any one of claims 115 to 124 or 127 to 129.

132. (Previously presented) A method of treating a mammal diagnosed with a modafinil-responsive disease or condition selected from the group consisting of narcolepsy, sleepiness, excessive sleepiness, excessive daytime sleepiness associated with narcolepsy, Parkinson's disease, urinary incontinence, multiple sclerosis fatigue, ADHD, Alzheimer's disorder, sleep apnea, obstructive sleep apnea, depression, and ischemia, said method comprising administering to said mammal one or more oral unit doses according to any one of claims 115 to 124 or 127 to 129.

133. (Previously presented) An oral dosage unit according to claim 86, that is bioequivalent to the modafinil drug product identified by the FDA as the reference listed modafinil drug.

134. (Newly added) An oral dosage unit of modafinil comprising solid modafinil particles, wherein more than about 5% of the modafinil particles in the dosage unit have diameters greater than 220 microns, and said dosage unit is bioequivalent to a modafinil dosage unit in which at least about 95% of the particles have diameters less than about 200 microns.

135. (Newly added) An oral dosage unit according to claim 134, wherein less than about 35% of the total cumulative number of particles are more than 220 microns in diameter.

136. (Newly added) An oral dosage unit according to claim 135, wherein between about 10% to about 30% of the total cumulative number of particles are more than 220 microns in diameter.

137. (Newly added) An oral dosage unit according to any one of claims 134 to 136, wherein said dosage form contains 100 mg of modafinil, and is bioequivalent to a 100 mg modafinil dosage unit in which at least about 95% of the particles are smaller than about 200 microns.

138. (Newly added) An oral dosage form according to any one of claims 134 to 136, wherein said dosage unit contains 200 mg of modafinil, and is bioequivalent to a 200 mg modafinil dosage form in which at least about 95% of the particles are smaller than about 200 microns.

139. (Newly added) An oral dosage form according to claim 138 that is bioequivalent to the modafinil drug product identified by the FDA as the reference listed modafinil drug.

140. (Newly added) A method of treating a condition using modafinil, the method of treating comprising:

providing an oral dosage unit according to claim 134.

141. (Newly added) A method according to claim 140, wherein said condition comprises one or more of narcolepsy and idiopathic hypersomnia.

142. (Newly added) A method of treating a mammal diagnosed with a modafinil-responsive disease or condition selected from the group consisting of narcolepsy, sleepiness, excessive sleepiness, excessive daytime sleepiness associated with narcolepsy, Parkinson's disease, urinary incontinence, multiple sclerosis fatigue, ADHD, Alzheimer's disorder, sleep apnea, obstructive sleep apnea, depression, and ischemia, said method comprising administering to said mammal one or more oral unit doses according to any one of claims 134 to 136.

143. (Newly added) A method according to claim 142 wherein said dosage form contains 100 mg of modafinil, and is bioequivalent to a 100 mg modafinil dosage unit in which at least about 95% of the particles are smaller than about 200 microns.

144. (Newly added) A method according to claim 142 wherein said dosage unit contains 200 mg of modafinil, and is bioequivalent to a 200 mg modafinil dosage form in which at least about 95% of the particles are smaller than about 200 microns.

145. (Newly added) A method according to claim 144 that is bioequivalent to the modafinil drug product identified by the FDA as the reference listed modafinil drug.